

IRB EFFICACY REVIEW

PRODUCT NAME: BLACK PEARL PASTE
PRODUCT FILE SYMBOL: 89670-R
REGISTRANT: Lodi Group
Grand Fougeray, France
DATE COMPLETED: 4/26/2016
DP NUMBER: 429823
DECISION NUMBER: 474788
DATES OF SUBMISSION: 9/25/2015 (received 9/25/2015), sent for review 10/26/15
ACTIVE INGREDIENTS: Alpha-chloralose
FORMULATION: 4.0% or 4.45% Alpha-chloralose paste
TYPE OF PRODUCT: Rodenticide
PURPOSE: Field efficacy study
DATA MRID NUMBERS: 497288-01
GLP CLAIMED: No
TEAM REVIEWER: Gene Benbow
EFFICACY REVIEWER: William W. Jacobs, Ph. D. *William W. Jacobs 4/26/16*
SECONDARY REVIEWER: Gene Benbow *Gene Benbow 4/26/16*

BACKGROUND

This product is a 4.0% or 4.45% "Alpha-chloralose paste formulation intended to be marketed in "pre-filled bait station (s)" and/or in 10-g "sachets" (to be placed in "**refillable bait stations**") proposed for U.S. registration under §3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended,

to control house mice and field mice inside homes, industrial, commercial, agricultural, and public buildings.

The bait-station component of this product is to be refillable, at least under one possible packaging arrangement. The front panel of the proposed "MASTER LABEL" bears the text "**THIS BAIT STATION IS NOT TAMPER RESISTANT**", which would put the bait-station version of this product in Tier 4 of the classification scheme for ready-to-use rodenticide bait stations that was put forth in EPA's 2008 Risk Mitigation Decision for Ten Rodenticides (RMD).

See efficacy review of 8/7/13 for this product and the efficacy review of 9/4/14 for 89670-E, which is a 90.27% Alpha-chloralose technical product proposed for registration for manufacturing purposes only.

See also the comments that I provided on various efficacy proposals and protocol transmitted on Lodi's behalf by its U.S.-based agents.

On 9/25/15, Jane Eickhoff of ToXcel Toxicology & Regulatory Affairs, a U.S. agent for Lodi Group, submitted a report of a single field efficacy study for EPA's perusal. That report was routed to me for review on 10/26/15. Along with the report, the review package includes a copy of a proposed label (dated "January 31 2013") and a copy of a pending Confidential Statement of Formulation (CSF) dated "**May 12, 2014**".

DATA SUMMARY

Formulation

See CONFIDENTIAL ATTACHMENT for a discussion of the pending formulation, as summarized on the CSF of 5/12/14.

Efficacy Study

The efficacy report submitted on 9/25/15 is cited and reviewed below.

Buczkowski, G. 2015. Field evaluation of Black Pearl Paste (alphachloralose) against the house mouse *Mus musculus*, in a confined livestock facility. Unpublished report, Summit Research and Consulting, West Lafayette, IN, 97 pp.

MRID No. 497288-01

This field trial was conducted at Purdue's "Swine Unit of the Animal Sciences Research and Education Center (ASREC)". Buczkowski describes the multi-building site as being heavily infested with house mice due to its run-down structural condition and the abundance of animal feed, manure, water, and harborage areas. In addition, the facility "was constructed on top of a known rodent infestation, when an old, heavily infested farm was abolished." Buczkowski reports that many different rodenticides have been used at the compound during its 4 decades of existence.

A "CERTIFICATE OF ANALYSIS" document from "LODIGROUP" that appears as "Page **88** of **97**" in the Buczkowski (2015) report states that "Batch Number: PA0140115" of "BLACK PEARL PASTE" was manufactured for "Customer: Grzegorz Buczkowski" on "2015-01-12". An analysis of that material for percent "Alpha-chloralose : 4.00 ± 10%" reportedly produced a result of "4.27%". See "CONFIDENTIAL ATTACHMENT" for additional discussion of the test material.

Buczkowski (2015) reports having used the Black Pearl Paste product within 5 of the buildings at the swine complex that were infested with house mice. According to the "**GLP COMPLIANCE STATEMENT**" page ("**3 of 97**"),

The enclosed study was not required to be conducted in compliance with EPA Good Laboratory Practice Standards (40 CFR Part 160). The study incorporated GLP standards to the extent possible.

Efficacy trials conducted to support claims for controlling vertebrate pests are supposed to be, and typically are, conducted in compliance with GLP standards.

The 5 buildings used for the trial included a "Swine Evaluation" building, the "Growing and Finishing II" building, the "Farrowing II" building, the "Breeding and Gestation II" building, and the "Open Front" building. Buczkowski (2015) provides information on the dimensions of rooms within these buildings and the areas in square feet of the rooms and the buildings but does not provide diagrams of them. At my request (e-mail note of 11/5/15), Eickhoff supplied, on 11/16/15, a "SUPPLEMENTAL INFORMATION" document for "**MRID 49728801**" which, among other things, includes computer-generated "**(NOT TO SCALE)**" schematics of the study rooms and bait placement locations. Detailed, hand-completed diagrams showing bait points, census points, and structural features within the buildings would have been far more helpful to this review. The schematics do indicate where 4 of the 5 buildings were divided internally into what Buczkowski referred to as "three separate rooms or 'zones'." No further details of

building contents are provided except for the designations “Mechanical Room” and “Lab” for the **“Breeding and Gestation II (BG II)”** building.

Buczkowski’s (2015) report states that this efficacy trial began on 3/8/15 and concluded on 4/15/15 but does not indicate the dates on which the various phases of the study began and ended. The “SUPPLEMENTAL INFORMATION” document supplied by Eickhoff on 11/16/15 includes a table that states that “phase I” (“pre-baiting”) began on 3/8/15 and concluded on 3/15/15; “phase II” (“toxic baiting”) began on 3/15/15 and ended on 3/29/15; “phase III” (“post-baiting”) ran from 4/3/15 to 4/7/15; and “phase IV” (“trap out”) lasted from 4/7/15 to 4/14/15. Between the “toxic baiting” and the “post-baiting” phases, there evidently was a 5-day lag period with no baiting or monitoring being reported. The narrative to Buczkowski’s report also mentions a 4-day lag period, between “pre-baiting” and “toxic-baiting”, that the table submitted subsequently does not mention or document.

Buczkowski reports having used 3 methods for assessing the activity of house mice before and after the period of bait exposure. These methods included live-trapping, census baiting, and tracking assessments. Tracking activity also was monitored during the bait-exposure phase. The post-treatment census period was followed by a trap-out phase during which time lethal snap-traps were deployed.

Census baiting was effected using Detex Blocks (20-g rodenticide-free bait blocks produced by Bell Laboratories, Inc., Madison, WI) placed in Protecta mouse-sized bait stations (another Bell product). Two Detex Blox were placed in each Protecta station. The Detex Blox used reportedly weighed “~20 g each”.¹ Amounts of census bait remaining were determined 24 hours after initial deployment. Two such census bait periods, two days apart, were employed during the pre-exposure phase (I) of the trial, and two more were employed during “Phase III”, following the bait-exposure phase (“II”). Census bait stations reportedly were spaced “approximately 10 feet apart in all buildings”.

Tracking activity was monitored using 6”-X-6” white floor tiles that had been sprayed with a mixture of “blue construction chalk” and isopropyl alcohol to impart a blue coating to each tile. The tiles were placed “in areas of high mouse activity” and checked for tracks 24 hours after deployment. To score activity, a grid of 36 one-inch squares was laid over each tile. The number of one-inch squares showing evidence of tracking was tallied and later divided by 36 to convert the total to a percent, which Buczkowski rounded to the nearest whole number (i.e., 3 squares of the 36 showing tracks was called 8% rather than 8.3% or 8.33%, etc.). As with census baiting, two 24-hour assessments of tracking activity were conducted during the “pre-baiting” and “post-baiting” phases. Buczkowski also assessed tracking activity 3, 7, and 14 days into the “toxic baiting” phase of the trial.

Buczkowski reports having used equal numbers of tracking tiles and census bait stations and that the census bait stations were deployed in places “different from” those where toxic bait stations were placed.

¹ On the data sheets for each census bait point, the amount of census bait deployed is entered as “41.30”. If each Detex Blox used weighed “~20 g” (which is consistent with Bell’s relevant claim for the product), it seems highly improbable that placing 2 of them per unit always would give the same pre-exposure net weight to the nearest 0.01 g. At the loci where zero consumption of census bait was reported, the weigh-back result also was reported as “41.30”. Information included in the “SUPPLEMENTAL INFORMATION” document supplied by Eickhoff suggests that Buczkowski weighed 30 Detex Blox and obtained a mean weight of 20.65 g with a standard deviation of 0.19 g and a range of 20.27 g to 21.02 g. None of the 30 Blox weighed exactly 20.65 g, although 2 of them did weigh 20.64 g. The universal amount-offered figure of 41.30 g evidently is the product of 2 times 20.65 g because 2 Blox were used per station for census baiting. As none of the Blox that actually were weighed came in at exactly 20.65 g, it is unlikely that the weights of many, if any, pairs of proffered Blox actually totaled 41.30 g. Therefore, it is likely that most, if not all, of the reportedly calculated census bait consumption figures were inaccurate to some degree. Given the variability in Blox weights, it seems unlikely that scored amounts “0” and “41.30” grams “consumed” were based upon actual weigh-backs. It seems more likely that such results were scored, respectively, when there appeared to be no census bait left or no disturbance of the 2 Blox placed in the Protecta unit. In his Tables 4A, 4B, 6A, and 6B, Buczkowski (2015) reports, for each room, what must be regarded as average per-station consumption estimates for the census bait to the nearest whole gram. Weigh-back results for each individual census-bait station are reported to the nearest 0.01 g.

Computer-generated diagrams in the "SUPPLEMENTAL INFORMATION" document schematically show the approximate locations of bait stations used for the toxic bait. Those diagrams are accompanied by text stating that "Toxic bait stations were placed approximately three feet from the location of each census station." It is not clear to what extent tracking tiles were located independently of census bait stations.

For the live-trapping census method, Buczkowski reportedly use one multi-catch mouse trap per room, which would have put 3 traps in each of 4 of the buildings and just one trap in one building. The trap used was the "JT Eaton 420CL" model. These traps were operated for two 12-hr periods (from 8 PM on one day to 8 AM on the next) during the "pre-baiting" and "post-baiting" phases of the study. Because the practice temporarily removes mice from the active population, live-trapping should not have been performed concurrently with other census methods (tracking and census baiting) as those indices would be suppressed somewhat by the removal of some individuals. As it provides no dates for the various pre- and post-treatment census activities, Buczkowski's (2015) report does not substantiate whether live-trapping was done concurrently with the other census methods.

For the "toxic baiting phase", "two sachets of the bait" were used per bait station. The bait station used was the "PAS CHEEZ 1 Tunnel bait station", which Lodi supplied along with the placepacks of "BLACK PEARL PASTE", as documented in the collection of "SUPPLEMENTAL INFORMATION". Buczkowski monitored bait consumption 1, 2, 3, 5, 7, 9, 11, and 14 days into the bait-exposure phase of the trial, adding that

If needed, fresh bait sachets were added on each inspection day to ensure that bait was always available in all stations.

According to Buczkowski's Table 5A, no replenishments of placepacks were made during the bait-exposure period. Tables provided with the Buczkowski (2015) report and in the "SUPPLEMENTAL INFORMATION" document are consistent with a conclusion that none of the bait stations was replenished during the baiting phase.

The number of bait stations used for toxic baiting was equal to the number used for census baiting.

Buczkowski reports having placed, in each of the 5 buildings one "weighed sachet" within each of 5 bait stations and having isolated the sachets from mouse contact by putting each loaded station "inside a plastic box with a screened lid to allow air movement." These "abiotic controls" were kept in place for the baiting period and then "reweighed to determine any changes in weight due to environmental conditions." Other information in the report and the "SUPPLEMENTAL INFORMATION" material is consistent with a total of 25 packs being used for these assessments. This type of procedure is appropriate for efficacy trials when bait, or census bait, consumption is being monitored.² As the test material used in this trial is

² Buczkowski's "Table 8. Results of abiotic control test" shows a range of 9.67-11.10 g and a mean of 10.34 g ("stdev" = "0.44") for the initial weights of the placepacks that were used in the assessment of weight gain or loss in the absence of feeding by mice. The weigh-backs of the 25 protected packs 14 days after placement showed a mean gain of 0.02 g, with 10 packs gaining a little weight, 3 losing a little, and 12 staying the same. However, the entries in "Table 5A. Consumption data from Phase II" which summarize reported consumption of toxic bait all show initial entries of "20.56", suggesting that each of the packs placed two to a station weighed exactly 10.28 g (or that the sum of the weights of the 2 packs always equaled 20.56 g), which would be unlikely. The "SUPPLEMENTAL INFORMATION" supplied by Eickhoff suggests that, separate from the "abiotic control test", Buczkowski weighed 30 "Black Pearl" packs and obtained a mean of 10.28 g with a standard deviation of 0.35 g and a range of 9.46 g to 11.05 g. None of these 30 sachets weighed exactly 10.28 g, although one of the 25 packs weighed for the "abiotic control test" did weigh 10.28 g. Multiplying 10.28 g by the number (2) of packs placed in stations for toxic baiting yields the 20.56-g figure that Buczkowski applied to all placements of toxic bait. In Buczkowski's Table 5A, weigh-back results for bait consumption taken at the end of the 14-day exposure period are reported to the nearest 0.01 g for individual units, with the per-unit average having been rounded to the nearest whole gram.

a “paste” formulation, moisture loss over time would be expected for it, unless it were sealed in a container such as a placepack.

Due to the almost certain inaccuracy of the initial placement amounts for the census-baiting index and the uncertainty regarding whether weigh-backs always were conducted, the data reported for this method are of questionable validity. Table 1 presents a summary of the census-bait consumption data using the mean amounts of consumption per station per building and per room within the building as reported by Buczkowski (2015) in his Tables 4A, 4B, 6A, and 6B. Because he rounded mean per-station consumption figures to the ones place, some “0” values appear in his tables, and consequently in Table 1 to this review, despite there having been some consumption of Detex Blox recorded during the post-treatment census period. The rooms for which post-treatment means of “0” were reported despite some post-treatment consumption of census bait include: Growing and Finishing II, Sows room, first post-treatment census; Growing and Finishing II, Main Barn, second post-treatment census; and Breeding and Gestation II, Main Room, second post-treatment census. As reported, the data suggest complete reductions on feeding on census bait following application of the toxic bait in 3 buildings and drastic reductions in feeding on census bait in the other two.

If conducted as described and accurate as reported by Buczkowski, the tracking index would be a valid measure of house mouse activity prior to, during, and after application of the toxic bait. Table 2 summarizes the tracking data according to the number of tracking squares (36 per tile) that were scored as active during the pre-treatment, treatment, and post-treatment phases of the trial. These data show complete reductions in tracking activity in the Swine Evaluation and Farrowing buildings and drastic reductions in such activities in the Growing and Finishing II, Breeding and Gestation II, and Open Front buildings.

Table 3 summarizes the live-trapping results reported by Buczkowski (2015) in his Tables 4A, 4B, 6A, and 6B. Although numbers of catches per room and per building in each of the pre-treatment rounds of trapping were low, the live-trapping results are consistent with effective control of house mice as suggested by the tracking results (Table 2). The value of live-trapping as an index to the level of house mouse activity would have been improved if more traps had been used per building. Apparently only one trap was used in the Farrowing building. If it was, live-trapping should not have been performed concurrently with the census-baiting and tracking indices.

The “CHEEZ 1” bait station used for exposing house mice to toxic bait in this trial is depicted on “Page 96 of 97” to the Buczkowski (2015) report. As shown, the unit appears to be longer than it is wide or high and to have an ample entryway for mice on one end, with the other end not shown in the picture. Text accompanying the picture gives the unit’s “**DIMENSIONS**” as “L 135mm x I 55mm x h 40mm”, which would make it ~6.1” long, ~2.2” wide and ~1.6” high. As unit’s internal construction is not shown, it is not clear whether or how the bait-containing sachets might have been secured within it or whether mice are required to negotiate any obstructions within the station in order to reach the bait pack. An example of this station should be examined prior to consideration of 89670-R for U.S. registration.

Buczkowski reports bait consumption data in Table 5A to his report. Due to the likely inaccuracy of the initial placement amounts, given as 20.56 g for each placement, the figures shown there for the individual stations and as per-room total likely are approximations of the actual consumption levels. Table 4 to this review summarizes the data reported per room for amounts of bait placed and calculated consumption (i.e., removal of bait from stations). Results for individual placements shown in Buczkowski’s Table 5A show that reported take from units ranged from no calculated consumption to removal of all “20.56” g. As Alpha-chloralose acts quickly to anesthetize house mice (often permanently), it is likely that most of the bait removal and consumption occurred very early in the bait-exposure period. Buczkowski (2015) states that

Periodic inspections of the bait stations throughout the toxic baiting period (days 2, 3, 5, 7, 9, 11, and 14) revealed that most of the bait consumed during the test was consumed during the first 24 h with virtually no consumption after the first 24 h. The first symptomatic mice were observed approximately 8 hours after the baits were deployed and virtually all dead mice were found on days 1 and 2. The dead mice were collected and discarded and no additional dead mice were found after the first 2 days.

Buczkowski does not provide a tally of the number of mouse carcasses found.

Buczkowski reports that

The bait was also attractive to ants, especially pavement ants (*Tetramorium caespitum*) which are attracted to oily bait formulations such as Black Pearl Paste. The ants were present in all test buildings and foraged within a large number of bait stations. Although the ants were frequently observed carrying pieces of bait back to their colonies, the amount removed is considered insignificant based on the abiotic control data provided in Table 9 [to his report].

No mice were caught in 4 of the 5 buildings during the trap-out phase (IV) of this study. Six mice were caught in the Breeding and Gestation II building. At least one mouse was caught in each room of that building, with 5 of the 6 caught having been taken on the first of the 7 trapping nights. That no mice were caught after the second trapping night suggests that snap-trapping of a few individuals greatly reduced mouse activity in the building and/or that the mice remaining, if any, were trap-shy.

The control estimates of 97-100% reported by Buczkowski (2015) greatly exceed EPA's criterion of at least 70% control in field trials involving lethal rodenticides.

Buczkowski's report includes information on temperature and relative humidity readings within the buildings. He reports an overall mean temperature of 26°C (79°F, with a range of 73-84°F) and a range of 45-68% for relative humidity, with a mean of 60%. Buczkowski's Table 2 presents single entries (presumably averages) for each of the rooms in the 5 buildings where the toxic bait was used. Because its effect on thermoregulation is critical to the toxicity of Alpha-chloralose to house mice, it is noteworthy that successful control of this species is reported at a site where the buildings apparently were maintained at or above typical "room" temperatures. It is not clear whether the nesting areas of mice were as warm as the room areas where bait was applied.

In addition to the problems with weights of census and toxic baits, the report of this trial suffers from a lack of pictures and detailed diagrams of buildings showing relationships among internal structures and placements of census and toxic bait points as well as tracking tiles. The report also lacks manually completed "raw" data forms. The most detailed of the data sheets included in report and/or the "SUPPLEMENTAL INFORMATION" document are computer-generated. According to the "**RAW DATA**" page (8) of the primary "SUPPLEMENTAL INFORMATION" document (as opposed to the link provided with it)

The data from the study were entered directly into an excel workbook, therefore, no raw data sheets are available. The tables in the report were copied from the spreadsheet directly into the report. Minor changes/clarifications were made to table headings or by adding footnotes to the tables in the report. An electronic copy of the laboratory workbook, named below, is being provided to EPA.

Summit – rodent test data – alphachloralose.xlsx

Although this likely "wave of the future" approach to data collection, processing, and reporting just described has certain built-efficiencies, it leaves reviewers with nothing tangible to substantiate that the research was performed, whether the entries made were accurate or valid, or whether any true corrections to entries were made.

LABEL

The label included in the efficacy review package is identified as the "Draft Label – January 31 2013." That label, which will be called the "pending label" in the apparent absence of evidence to the contrary, corresponds in text, but not in font, to the label appended to Buczkowski's (2015) report as pages "90" through "93".

On the pending label, the "**DIRECTIONS FOR USE**" section includes sets of "**APPLICATION DIRECTIONS: For pre-baited stations**" and "**APPLICATION DIRECTIONS: For refillable bait stations**". In the context provided by the 3 numbered directions that follow it, the former designation refers to a single-use, non-refillable, ready-to-use bait station product. In contrast and in the context

provided for it, “**APPLICATION DIRECTIONS: For refillable bait stations**” seems to refer to a ready-to-use bait-station product that is refillable, perhaps with additional sachets included in the retail package. Historically and currently, EPA has regarded refillable and non-refillable ready-to-use rodenticide bait stations as distinct products for which separate §3 registrations would be required. Thus, Lodi would have to decide which one of these types of product the company would prefer File Symbol 89670-R to be and to apply for a second end-use product registration for the other of these types, if that also were desired. For reasons developed below, Lodi also might want to consider registering the Black Pearl Paste product in placepack (sachet) form under labeling that would direct its marketing toward commercial and structural agricultural users.

Now that some efficacy data from a US-based trial have been supplied, work on improving the label’s use directions and claims of effectiveness can begin in earnest. The field trial results reported by Dr. Buczkowski suggest that there is a way to achieve very good control of house mice through use of the Black Pearl Paste product, as it was formulated, provided to, and used by him. Buczkowski obtained bait stations and placepacks as distinct units. Thus, he applied the product as a commercial user probably would and also (arguably) as one obtaining a refillable, ready-to-use bait station product might, under the two-pack-per-unit option.

A commercial user obtaining sachets of bait separately from bait stations would, under appropriate product labeling, have more flexibility in using the product. The commercial user would not be limited to making applications out of reach of children, pets, and other nontarget animals in the “**NOT TAMPER RESISTANT**” CHEEZ 1 unit because the user would know where to obtain tamper-resistant bait stations and likely would have some inventory of such units on hand. The commercial user also would be able to deploy the tamper-resistant stations prior to actual use of the toxic bait so as to condition mice to enter and feed from them in order to promote high rates of visitation and consumption when sachets of toxic bait were added. Although the material, the bait station design, and the placement location were not identical in the Buczkowski (2015) study, some preconditioning of house mice to enter and feed from bait stations might have enhanced the speed and near completeness of the outcome reported for that trial. If Lodi were to supply a true placebo prebait for Black Pearl Paste, initial uptake of the toxic material and, therefore, its impact likely would be maximized. In general, however, house mice are more likely to be curious rather than fearful of objects newly added to their environment than is the case with Norway rats (*Rattus norvegicus*) and roof rats (*R. rattus*).

Specific comments on the use directions and efficacy-related claims on the pending label appear under CONCLUSIONS.

CONCLUSIONS

1. The efficacy report by Buczkowski (2015, MRID No. 497288-01) suggests that the experimental use of the test material, Black Pearl Paste, resulted in very effective reduction of house mouse activity and numbers at five buildings on Purdue University’s swine complex. This study is accepted with reservations due to the following issues:
 - a) the data reported as initial placement amounts for census bait and toxic bait were based upon doubling of the average weights of Detex Blox and bait sachets rather than the actual weights of the amounts offered in each bait station; and
 - b) neither the report nor information supplied subsequently includes diagrams showing accurate representations of the locations of census-bait stations, tracking stations, or toxic-bait stations within the five buildings.
2. Submit a formulation (batch) sheet that documents the composition of the specific lot of Black Pearl Paste (“Batch Number: PA0140115”) that was used in Dr. Buczkowski’s (2015) study.
3. The pending “Draft Label – January 31 2013” bears directions for a refillable ready-to-use bait-station product and a single-use (non-refillable) ready-to-use bait station product. Products of those types must be registered separately from one another.

4. Delete "and field mice" from the phrase "Rodenticide bait for effective control of house mice and field mice" that appears on page 1 of the label, directly below the name of the product.
5. Delete ", and" from the phrase "Use Indoors only, and in Areas Inaccessible to Children and Pets" that appears on page 1 of the label, directly below **"THIS BAIT STATION IS NOT TAMPER-RESISTANT"**.
6. Directly after **"IMPORTANT:"** in the **"DIRECTIONS FOR USE"** section (page 2), insert the sentence **"THIS BAIT STATION IS NOT TAMPER-RESISTANT"**.
7. Delete "and field mice" from the first sentence of the **"USE RESTRICTIONS:"** paragraph.
8. If this product is to be a single-use (non-refillable) ready-to-use bait station, replace the **"APPLICATION DIRECTIONS: For pre-baited stations"** with the text shown below and delete all text pertaining to **"APPLICATION DIRECTIONS: For refillable bait stations"**.

APPLICATION DIRECTIONS:

- 1) Apply one bait station every 6 to 16 feet in selected treatment area.
 - 2) Check bait stations daily or every two days for signs of bait consumption and other house mouse activity. Keep stations in place for at least 7 days. Replace bait stations if their contents have been depleted and/or if they have become soiled or damaged. Remove and properly dispose of bait stations that are soiled, no longer contain bait, or no longer are needed.
 - 3) Wear waterproof gloves when placing, retrieving, replacing, or disposing of bait stations and when retrieving and disposing of carcasses or cleaning up bait that has come out of bait stations.
9. If this product is to be a refillable ready-to-use bait station, replace the **"APPLICATION DIRECTIONS: For refillable bait stations"** with the text shown below and delete all text pertaining to **"APPLICATION DIRECTIONS: For pre-baited stations"**.

APPLICATION DIRECTIONS:

- 1) Establish one bait station every 6 to 16 feet in selected treatment area.
 - 2) Wearing waterproof gloves, insert 1 or 2 sachets of bait inside each bait station. Use 2 sachets only at points of extremely high house mouse activity.
 - 3) Check bait stations daily or every two days for signs of bait consumption and other house mouse activity. Keep stations in place for at least 7 days. Refill bait stations with 1 or 2 sachets if their contents have been depleted. Remove and properly dispose of stations if they have become soiled or damaged.
 - 4) Wear waterproof gloves when placing, retrieving, replacing, or disposing of bait stations and when retrieving and disposing of carcasses or cleaning up bait that has come out of bait stations.
10. The comments immediately below apply to the "[Additional Optional Marketing/Advertising Claims]" (page 5).
- a) In the second item, change "Alphachloralose" to "Alpha-chloralose" (to match the label's statement of ingredients).
 - b) Delete the fifth item or change it to read "This product may be used in garages if use is consistent with the requirements in the **DIRECTIONS FOR USE**."
 - c) If the "Bait station conceals bait from view" (eighth item), how does one inspect it for evidence of consumption? Submit an example of the bait-station component of this product.

- d) Delete the 16th and 17th items. Claims of efficacy against anticoagulant-resistant organisms must be substantiated with appropriate efficacy studies.
11. Submit a label for the individual bait sachets if the product is to be refillable or to be sold as sachets only to commercial and/or structural agricultural users.

Table 1. Pre- and post-treatment census-bait consumption reported by Buczkowski (2015, MRID No. 497288-01) in Tables 4A, 4B, 6A, and 6B.

Building	Room	No. of Stations in Room	Pre-treatment			Post-treatment			Percent Change from Pre-treatment
			Mean g Taken Period 1	per Station Period 2	2-Period Average	Mean g Taken Period 1	per Station Period 2	2-Period Average	
Swine Evaluation	East	20	29	31	30	0	0	0	-100%
	West	20	26	32	29	0	0	0	-100%
	Prep	17	34	27	30.5	0	0	0	-100%
	3-room Total	57	89	90	89.5	0	0	0	-100%
Growing and Finishing II	Feed	12	33	32	32.5	1	1	1	-97%
	Sows	19	37	31	34	0	0	0	-100%
	Main Barn	38	32	34	33	0	0	0	-100%
	3-room Total	69	102	97	99.5	1	1	1	-99%
Farrowing	Main Barn	25	19	24	21.5	0	0	0	-100%
Breeding and Gestation II	Main	10	32	37	34.5	2	0	1	-97%
	Boars	24	36	34	35	1	1	1	-97%
	Sows	20	41	41	41	0	2	1	-98%
	3-room Total	54	109	112	110.5	3	3	3	-97%
Open Front	Main	12	37	36	36.5	0	0	0	-100%
	Side Room 1	7	41	41	41	0	0	0	-100%
	Side Room 2	7	17	22	19.5	0	0	0	-100%
	3-room Total	26	95	99	97	0	0	0	-100%

Note: Data reported are means taken to the ones place. Consequently, some of the "0" values do not reflect complete absence of post-treatment take (e.g. Main Room in Breeding and Gestation II building and Main Barn in Growing and Finishing II for their second post-treatment censuses).

Table 2. Pre-, during- and post-treatment tracking activity reported by Buczkowski (2015, MRID No. 497288-01) in Tables 4A, 4B, 5B, 6A, and 6B.

Building	Room	No. of Stations in Room	No. of Squares Examined	Pre-treatment			Bait Day 3 Active	Exposure Day 7 Active	Phase Day 14 Active	Post-treatment			Percent Change from Pre-treatment
				Period 1 No. Active	Period 2 No. Active	2-Period Average				Period 1 No. Active	Period 2 No. Active	2-Period Average	
Swine Evaluation	East	20	720	449	415	432	0	0	0	0	0	0	-100.0%
	West	20	720	440	448	444	0	0	0	0	0	0	-100.0%
	Prep	17	612	304	379	341.5	0	0	0	0	0	0	-100.0%
	3-room Total	57	2052	1193	1242	1217.5	0	0	0	0	0	0	-100.0%
Growing and Finishing II	Feed	12	432	305	311	308	0	0	0	11	14	12.5	-95.9%
	Sows	19	684	491	498	494.5	0	0	0	3	0	1.5	-99.7%
	Main Barn	38	1368	885	972	928.5	0	0	0	0	8	4	-99.6%
	3-room Total	69	2484	1681	1781	1731	0	0	0	14	22	18	-99.0%
Farrowing	Main Barn	25	900	299	457	378	0	0	0	0	0	0	-100.0%
Breeding and Gestation II	Main	10	360	324	326	325	11	5	19	8	2	5	-98.5%
	Boars	24	864	807	757	782	13	0	0	17	0	8.5	-98.9%
	Sows	20	720	693	663	678	0	0	9	0	5	2.5	-99.6%
	3-room Total	54	1944	1824	1746	1785	24	5	28	25	7	16	-99.1%
Open Front	Main	12	432	413	393	403	17	7	0	0	0	0	-100.0%
	Side Room 1	7	252	231	234	232.5	0	0	0	0	0	0	-100.0%
	Side Room 2	7	252	147	170	158.5	0	0	0	0	0	0	-100.0%
	3-room Total	26	936	791	797	794	17	7	0	0	0	0	-100.0%

Table 3. Live-trapping and trap-out results reported by Buczkowski (2015, MRID No. 497288-01) in Tables 4A, 4B, 6A, 6B, and 7.

Building	Room	No. of Traps in Room	Pre-treatment Live Catch			Post-treatment Live Catch			Percent Change from Pre-treatment	Trap-Out Snap-trap Catch
			Mice Caught Period 1	Mice caught Period 2	2-Period Average	Mice Caught Period 1	Mice Caught Period 2	2-Period Average		
Swine Evaluation	East	1	3	2	2.5	0	0	0	-100%	0
	West	1	1	1	1	0	0	0	-100%	0
	Prep	1	2	2	2	0	0	0	-100%	0
	3-room Total	3	6	5	5.5	0	0	0	-100%	0
Growing and Finishing II	Feed	1	3	1	2	0	0	0	-100%	0
	Sows	1	4	2	3	0	0	0	-100%	0
	Main Barn	1	3	4	3.5	0	0	0	-100%	0
	3-room Total	3	10	7	8.5	0	0	0	-100%	0
Farrowing	Main Barn	1	2	1	1.5	0	0	0	-100%	0
Breeding and Gestation II	Main	1	5	2	3.5	0	0	0	-100%	4
	Boars	1	5	5	5	0	0	0	-100%	1
	Sows	1	4	3	3.5	0	0	0	-100%	1
	3-room Total	3	14	10	12	0	0	0	-100%	6
Open Front	Main	1	3	2	2.5	0	0	0	-100%	0
	Side Room 1	1	0	1	0.5	0	0	0	-100%	0
	Side Room 2	1	2	0	1	0	0	0	-100%	0
	3-room Total	3	5	3	4	0	0	0	-100%	0

Table 4. Toxic-bait removal reported by Buczkowski (2015, MRID No. 497288-01) in Tables 4A, 4B, 6A, and 6B.

Building	Room	No. of Stations in Room	Total Bait Offered (g)	Treatment Total Bait Take (g)	Percent of Bait Removed
Swine Evaluation	East	20	411	96	23.4%
	West	20	411	68	16.5%
	Prep	17	350	48	13.7%
	3-room Total	57	1172	212	18.1%
Growing and Finishing II	Feed	12	247	68	27.5%
	Sows	19	391	54	13.8%
	Main Barn	38	781	210	26.9%
	3-room Total	69	1419	332	23.4%
Farrowing	Main Barn	25	514	172	33.5%
Breeding and Gestation II	Main	10	206	90	43.7%
	Boars	24	493	189	38.3%
	Sows	20	411	195	47.4%
	3-room Total	54	1110	474	42.7%
Open Front	Main	12	247	77	31.2%
	Side Room 1	7	144	31	21.5%
	Side Room 2	7	144	22	15.3%
	3-room Total	26	535	130	24.3%